

REMARKS

I. Claims Status

Claims 23, 26, 28, 30-34, 37-40, 44, 46-50, and 57-59 are pending in the application. Claims 23, 28, 34, 37-40, 44, 46, and 59 are sought to be amended. None of these changes are believed to introduce any new matter, and their entry is respectfully requested.

Claim 23 has been amended to recite "said part having a length of at least 120 nucleotides," which finds support in Applicants' specification, for example, at page 5, lines 27-51.¹ Claim 23 has also been amended to recite "wherein the percent homology is determined by (a) globally aligning the nucleotide sequence to nucleotides 206 - 2603 of SEQ ID NO: 1, (b) adding up the aligned nucleotides that are identical to obtain a number of identical globally aligned nucleotides, (c) dividing the number of said identical globally aligned nucleotides by 2398 to obtain a ratio, and (d) multiplying the ratio by 100 thereby obtaining the percent homology . . ." Applicants respectfully assert that this determination of homology would be self-evident to the skilled artisan upon inspection of Figure 1a. Figure 1a shows that the reference sequence (nucleotides 206 to 2603 of SEQ ID NO.: 1) is 2,398 nucleotides long. The reported homologies were determined as defined by the amended claim. For example, the *H. felis* nucleotide sequence that encodes UreA and UreB (identified in Figure 1a as "*H. felis* com") has 1,604 nucleotides that are identical to the reference nucleotide sequence (identified in Figure 1a as "Cs1seq"). 1,604 divided by 2398 multiplied by 100 is about 66.8%, which is about 67%. The remaining homologies in Figure 1a were determined in this manner.

Claim 34 has also been amended to recite "wherein the percent homology is determined by (a) globally aligning the amino acid sequence to SEQ ID NO: 2, (b) adding up the aligned amino acids that are identical to obtain a number of identical globally aligned amino acids, (c) dividing said number of identical globally aligned amino acids by 226 to obtain a ratio, and (d) multiplying said ratio by 100 thereby obtaining the percent homology . . ." Applicants

¹ Applicants note that the specification text refers to 40 amino acids, which necessarily corresponds to 120 encoding nucleotides.

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respectfully assert that this determination of homology would be self-evident to the skilled artisan upon inspection of Figure 1b. Figure 1b shows that the reference sequence (SEQ ID NO.: 2, identified as "ureXCS1") is 226 amino acids long. The reported homologies were determined as defined by the amended claim. For example, the *H. felis* UreA amino acid sequence (identified in Figure 1b as "A felis") has 113 amino acids that are identical to the reference amino acid sequence (identified in Figure 1b as "ureXCS1"). 113 divided by 226 multiplied by 100 is 50%. The remaining homologies in Figure 1b were determined in this manner.

Claim 40 has also been amended to recite " wherein the percent homology is determined by (a) globally aligning the amino acid sequence to SEQ ID NO: 3, (b) adding up the aligned amino acids that are identical to obtain a number of identical globally aligned amino acids, (c) dividing said number of identical globally aligned amino acids by 568 to obtain a ratio, and (d) multiplying said ratio by 100 thereby obtaining the percent homology" Applicants respectfully assert that this determination of homology would be self-evident to the skilled artisan upon inspection of Figure 1c. Figure 1c shows that the reference sequence (SEQ ID NO.: 3, identified as "ureYCS1") is 568 amino acids long. The reported homologies were determined as defined by the amended claim. For example, the *H. felis* UreB amino acid sequence (identified in Figure 1c as "B felis") has 412 amino acids that are identical to the reference amino acid sequence (identified in Figure 1c as "ureYCS1"). 412 divided by 568 multiplied by 100 is 72.53%, or about 73%. The remaining homologies in Figure 1b were determined in this manner.

Claim 46 has been amended by addition of the recitation "under the control of a promoter that is operably linked to said nucleic acid molecule," which finds support in Applicants specification, for example, at page 3, lines 42-46.

All other amendments are made to clarify the claims and find support in the specification or claims as originally filed.

II. Maintained Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 46-49 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabled by the specification. Office Action, pages 3-5. Solely to expedite prosecution and not in

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acquiescence to the rejection, Applicants have amended claim 46 to include the recitation "under the control of a promoter that is operably linked to said nucleic acid molecule." Accordingly, Applicants believe that this rejection is now moot and respectfully request that the examiner reconsider and withdraw the rejection.

III. Maintained Rejections Under 35 U.S.C. § 102(b)

Claims 23, 26, 28, 30-34, 37-40, 44, 46-50 and 57-59 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Labigne *et al.* (U.S. Pat. No. 5,843,460). Office Action, pages 6-9. Applicants respectfully traverse the rejection.

Solely to expedite prosecution and not in acquiescence to the rejection, Applicants have amended claims 23, 34 and 40 to clarify the scope of homologous sequences encompassed by the claims and thereby distinguishing the claims from anything described by Labigne *et al.* Accordingly, Applicants now believe that this rejection is moot and request that the Examiner reconsider and withdraw the rejection.

Applicants further note that Labigne *et al.* pertains to *H. pylori* UreA and UreB ureases, as well as *H. felis* UreA and UreB ureases. See column 2, lines 14-35. Applicants' specification acknowledges these four ureases, and specifically references Labigne *et al.*'s published International Patent Application No. WO 96/34624. See Applicants' specification, page 1, lines 25-27. WO 96/34624 is related to U.S. Patent No. 5,843,460, as both claim priority to U.S. Application Nos. 08/447,177 and 08/432,697. Indeed, Applicants' specification includes a sequence alignment between their novel UreX and UreY proteins and Labigne *et al.*'s UreA and UreB proteins. See page 2 of Applicants' specification, and figures 1a, 1b and 1c. Hence, it is clear from Applicants' specification that the claims do not encompass the UreA and UreB proteins described by Labigne *et al.*

Accordingly, Labigne *et al.* does not anticipate Applicants' claimed invention. Thus, Applicants request that the Examiner reconsider and withdraw the rejection.

III. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 23, 26, 28, 30-34, 37-39, 40, 44, 46-50 and 57-59 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Office Action, page 10-12. Applicants respectfully traverse the rejection.

In contrast to the Examiner's remarks on page 11, Applicants are not claiming antigenic epitopes of 3-10 amino acids. Rather, the immunogenic fragments of Applicants claims must be at least 70 amino acids long. Moreover, Applicants' specification describes methods at page 6, line 32 to page 7, line 8 that would be readily understood by the skilled artisan. Given this description, the novel sequences described by Applicants and the state of the art, the skilled artisan would readily appreciate that Applicants had adequately described the claimed immunogenic fragments. Hence, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

IV. Maintained Rejections Under 35 U.S.C. § 102(b)

Claims 23, 26, 28, 30, 33, 34, 37-39, 40, 44, and 57-59 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gootz *et al.* (1994). Office Action, pages 12-14. The Examiner apparently interprets Gootz *et al.* as describing *H. felis* UreX and UreY proteins. Applicants respectfully disagree with the Examiner's interpretation and the corresponding rejection.

Gootz *et al.* states in the last line of the abstract: "A probe to the putative coding sequence for the active site of the *H. pylori* ureB subunit hybridized at low intensity to a 2.8-kb fragment of Bam HI-HindIII-digested *H. felis* DNA, suggesting that the sequences were homologous but not identical, a result confirmed from the recently published sequences of ureA and ureB from *H. felis*." Hence, the *H. felis* urease proteins identified by Gootz *et al.* are homologous to the *H. pylori* ureA and ureB proteins. Indeed, Gootz *et al.* refers specifically to Labigne *et al.*'s publications when comparing the *H. felis* ureA and ureB proteins. See Discussion, and references 14 and 15.

Thus, the *H. felis* urease proteins identified by Gootz *et al.* must be UreA and UreB, and not the novel and unobvious proteins now identified and claimed by Applicants. In contrast to Gootz

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et al., Applicants' *H. felis* ureX and ureY proteins are not homologous to either the *H. pylori* or the *H. felis* ureA or ureB proteins. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

V. New Written Description Rejection Under 35 U.S.C. §112, First Paragraph

Claims 34, 37-38, 50 and 57 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Office Action, page 14. In particular, the Examiner states that original descriptive support could not be found for the recited percent homologies. *Id.* Applicants respectfully traverse this rejection.

Support for these claims can be found in the originally presented claims 34, 37 and 38, which were first presented in a Preliminary Amendment filed on July 13, 2001. A copy of the Preliminary Amendment, bearing U.S. Postal Service Express Mail Envelope No. EL 400659575 US is provided herewith as Exhibit A. Although this Preliminary Amendment was accidentally dated July 17, 2001, the Express Mail label, Utility Patent Application Transmittal form and Fee Transmittal form all indicate that all parts of this Express Mail package were submitted on July 13, 2001, which is Applicants' file date. See Exhibit B.²

Accordingly, the claims are fully supported and Applicants request that the Examiner reconsider and withdraw the rejection.

CONCLUSION

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the

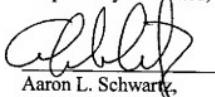
² Applicants note that claim 38 in the Preliminary Amendment has an obvious typographical error: it depends from claim 31. This obvious typographical error was corrected in a Supplemental Preliminary Amendment deposited with the U.S. Postal Service on August 20, 2001.

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Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Applicants submit that this application is in condition for allowance, and request that it be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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